DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 17 2012

Re: KRYSTEXXA
Docket No.: FDA-2011-E-0168

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,783,965, filed by Mountain View Pharmaceuticals, Inc., and Duke University, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for KRYSTEXXA (pegloticase), the human biological product claimed by the patent.

The total length of the regulatory review period for KRYSTEXXA is 3,193 days. Of this time, 2,509 days occurred during the testing phase and 684 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: December 19, 2001.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 19, 2001.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: October 31, 2008.

   FDA has verified the applicant's claim that the biologics license application (BLA) for KRYSTEXXA (BLA 125293) was initially submitted on October 31, 2008.

3. The date the application was approved: September 14, 2010.

   FDA has verified the applicant's claim that BLA 125293 was approved on September 14, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Eldora Ellison Floyd & Helene C. Carlson
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